UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,893	10/14/2003	J. Milton Harris	044646/262893	4856

826 7590 03/30/2009

ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,893	HARRIS, J. MILTON	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17* is/are rejected.

7)☒ Claim(s) *15 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on December 9 2008 is acknowledged. Claims 14 were/stand cancelled. Claims 1-13 and 15-27 are pending. Claims 25-27 are withdrawn as being directed to a non-elected invention. Claims 1-13 and 15-24 are directed to the elected invention. The examiner would like to note that the search has been expanded to include all species of the hydrolysable linkages. Therefore, previously withdrawn claims 15-17 are examined on the merits herein as well.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 15-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 9, 17-18 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses polymer, such as

$$\{R[CH_2\text{-O-PEG-W-PEG-W-}]_p\}_m,$$

$$\{R[CH_2\text{-O-PEG-X-PEG-W-PEG-X-}]_p\}_m, \text{ and}$$

$$\{R[CH_2\text{-O-PEG-X-R'-W-PEG-W-R'-X-}]_p\}_m,$$

which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1-8, 9, 17-18 and 23-24 are directed to encompass any crosslinked polymeric structure comprising poly(ethylene glycol) comprising some hydrolytically unstable linkages, which only correspond in some undefined way to specifically instantly disclosed chemicals. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what the polymers are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Note: MPEP 2163.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed crosslinked polymers, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Circ. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Since independent claim 1 provides no description as to where the hydrolytically unstable linkages would occur as well as where the crosslinking would occur, only the above chemically structurally defined chemicals, but not the full breadth of the claims meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claims 1-6, 9-10 and 23-24 are additionally rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the following additional reason.

The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses linkages such as carboxylate esters, phosphate esters, glycerol, etc. which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1-6, 9-10 and 22-24 are directed to encompass all peptides and oligonucleotides.

Note: MPEP 2163. For claims drawn to a genus, which is peptide and delivered agent in the instant application, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure of relevant identifying characteristics sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]. *Enzo Biochem,* 323 F.3d at 966,63 USPQ2d at 1615 (Fed. Cir. 2004) and *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69, USPQ2d 1508, 1514 (Fed. Cir. 2004). Furthermore the MPEP clearly indicates that the disclosure of a species does not suffice to provide written description support for the genus. *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833 (Fed. Cir. 1998).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.").

For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. *Eli Lilly,* 119 F.3d at 1568, 43 USPQ2d at 1406 9Fed. Cir.

1997). If a representative number of adequately described species are not disclosed for a genus, the claim(s) to that genus must be rejected as lacking adequate written description.

The instant specification claims polymer structures comprising hydrolytically unstable linkages. These unstable linkages include oligonucleotides and peptides. However, the instant specification provides neither examples nor any description as to what oligonucleotides or peptides are encompassed by the instant invention. Since oligonucleotides and peptides structures are highly variant, the resulting genus is not supported by the instant disclosure.

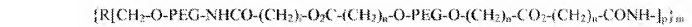
Therefore, the full breadth of the claims do not meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-14 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 as currently written is vague and indefinite. The claim recites a structure having the following formula:



However, the claim depends from claim 1 and neither claim 1 nor claim 20 provide a definition for the group R. Therefore, it is unclear what the R group stands for in claim 20.

Claim 21 as currently written is vague and indefinite. The claim recites a structure having the following formula:

However, the claim depends from claim 1 and neither claim 1 nor claim 21 provide a definition for the group R or group W. Therefore, it is unclear what the R group and the W group stands for in claim 21.

Claims 1, 10-12 and 22 as currently written are vague and indefinite. Claim 1 recites that the hydrolytically unstable linkages include oligonucleotides. Claim 10 indicates that the hydrolytically unstable linkages include peptides and oligonucleotides. Claim 12 recites the formation of peptide linkages with PEG-peptide conjugates terminated with amine and oligonucleotide linkages that are the reaction product of a phosphoramidite with a hydroxyl terminated PEG oligonucleotide. Claims 11 and 22 recite that the R moiety includes glycerol oligomers. All of these groups (oligonucleotides, peptide and glycerol oligomers) are components that make up the claimed polymeric structure. Oligonucleotides, peptides, and glycerol oligomers are by definition polymers. An oligonucleotide is a polymer of nucleic acids, a peptide is a polymer of amino acids and glycerol oligomers are polymers of glycerol. However claim

1 indicates that the polymeric structure comprises PEG polymers in the absence of non-PEG polymers. Therefore, it is unclear how oligonucleotides, peptides and glycerol oligomers can be components of the polymeric structure when non-PEG polymers are expressly excluded from the polymeric structure.

Claim 1 is additionally rejected as being vague and indefinite as it recites that the polymeric structure comprises at least "some" hydrolytically unstable linkages. The instant specification provides no definition for the word some. Therefore, it is unclear because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired for the number of hydrolytically unstable linkages present in the polymeric structure.

Claims 2-6, 9, 12-14, 23 and 24 are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims

2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-9, 17-18 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamiolkowski et al. (US Patent No. 5698213)is **withdrawn** in light of Applicant's argument that Jamiolkowski et al. is only available as prior art as of the filing date priority document (US Patent 5607687) and that this document does not teach that the polymer form hydrogels.

Claims 1-10, 12-13, 17-19 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al. (US Patent No. 5648506, cited on PTO Form 1449).

Applicant Claims

Applicant claims a hydrogel crosslinked polymeric structure comprising poly(ethylene glycol) (PEG) polymers in the absence of non-PEG polymers. The PEG polymers have at least some hydrolytically unstable linkages between said PEG polymers that are hydrolysable under hydrolysis conditions, said hydrolysable linkages comprising linkages selected from the group consisting of carboxylate esters, phosphate esters, imines, hydrazones, acetals, orthoesters, and oligonucleotides.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Desai et al. is directed to water-soluble polymer carriers for Drug Delivery. The invention relates to the drug delivery of taxol wherein the drug is chemically bound to a

water-soluble polymer or macromolecular carrier that renders the drug water-soluble (column 1, liens 10-20). It is taught that the preparation of reversible PEG-taxol derivative at the 2' and/or 7-position on taxol serves as useful aqueous soluble prodrug. A nonreversible PEG derivative on the 7-position of taxol serves as a useful water-soluble drug analogue (column 2, lines 32-37). In a preferred embodiment, taxol is covalently linked to a PEG carboxylic acid derivative by an esterification at the 2'-position on the taxol side chain (i.e. reaction with taxol alcohol at the 2' position) (column 3, lines 10-12). It is taught that other drugs may be utilize din a similar form of drug delivery (column 4, lines 25-26). It is taught that the purpose of covalently linking a water-insoluble or poorly water-soluble drug to a water-soluble polymer is to solubilize the drug in water to enable its delivery in a soluble form into the body (column 4, lines 37-40). As exemplified in table 1, peg polymers were attached to taxol via amide linkages (compound 3) or ester linkages (compound 7). PEG was linked to taxol with relatively stable urethane linkages at the 7 position as coupling of PEG with stable linkages at the 2' position would be expected not to have a high biological activity (column 5, lines 35-45). Alternatively PEG could be attached at the 2' position of taxol with hydrolysable ester linkages to release taxol in an active form after delivery of the drug (column 5, liens 59-64). In these examples the number of drug molecules per carrier is restricted to a maximum of two taxol molecules per molecule of PEG and only one taxol per MPEG. In order to increase the number of taxols per carrier molecule, PEGS with multiple arms such as branched molecules or star molecules are utilized (column 6, lines 27-32). One such 'star molecules' in one that has an oligomeric

glycerol central core that is ethoxylated and used to initiate polymerization of ethylene oxide and then quenched when the desired molecular weight is achieved (column 7, lines 7-10). Examples 1-4 teach linking taxol to PEG at either the 2, 7 or both linkage sites via either hydrolytically stable urethane linkages or hydrolysable ester linkages. Example 5 is directed to the use of a branched chain or "start' PEG for multiplicity of attachment sites. It is taught that the reactions described in examples 1 through 4 can be utilized to covalently attach drugs to these molecules. Example 7 is directed to a hydrogel containing bound taxol for sustained release drug delivery. It is taught that the derivative is crosslinked.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

While Desai et al. teach that core of the 'star' molecules with peg arms can be oligomeric glycerol, Desai et al. do not exemplify this star molecule with taxol attached. While Desai et al. teach that taxol can be linked to PEG via hydrolytically unstable ester linkages or hydrolytically stable urethane linkages and suggests both can be utilized, Desai et al. do not exemplify structures with both.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize both hydrolytically unstable ester linkages and hydrolytically stable urethane linkages in the connection of PEG to taxol. One of ordinary skill in the art would have been motivated to utilize both as Desai et al. teach that taxol can be linked to PEG in either manner and suggests that hydrolytically unstable linkages can

provide a releasable form of taxol. Since the linkage of PEG with taxol is designed to enhance the water solubility of the drug for delivery and that the free OH at the 2 position is required for activity it would have been obvious to one of ordinary skill in the art to attach taxol to PEG at the 2 position in order to provide a hydrolysably releasable taxol moiety and to attach taxol to PEG at the 7 position in order to maintain the water solubility of the taxol moiety after delivery as taught by Desai et al.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize a glycerol oligomer as the core for the branching star group of PEG linkages. One of ordinary skill in the art would have been motivated to utilize a glycerol oligomer as it is specifically taught by Desai et al. as one type of core that can be utilized to attach PEG polymers. Furthermore, it would have been obvious to one of ordinary skill in the art to attach taxol to these PEG star molecules utilizing both ester and urethane linkages as Desai et al. teach that either of these types of linkages can be utilized to attach taxol (or other drugs) to the star molecules.

Regarding the claimed crosslinking, the instant claims indicate that the PEG polymers are crosslinked in the absence of photopolymerization or free-radical polymerization. This limitation is interpreted as a product by process limitation. **Note MPEP 2113 [R-1]** "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different

process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The MPEP also indicates that "the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Therefore, as long as the final product is the same as instantly claimed, the crosslinking does not have to be the same as instantly claimed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting/Terminal Disclaimer

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-13 and 15-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6258351 is **withdrawn** in light of Applicant's filing of a terminal disclaimer on December 9 2008.

The terminal disclaimer filed on December 9 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6258351 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616